

DOCKET NO: 271390US0PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :  
KEI KIRIBAYASHI, ET AL. : EXAMINER: HENRY, M.C.  
SERIAL NO: 10/533,538 :  
FILED: MAY 2, 2005 : GROUP ART UNIT: 1623  
FOR: PERITONEAL DIALYSIS :  
METHOD

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The Applicants request review of the final rejection in the above-identified application.

No amendments are being filed with this request.

This request is being filed with a Notice of Appeal.

The review is requested for the reasons stated on the attached sheets.

No more than five (5) pages are provided.

I am the attorney or agent of record.

Respectfully Submitted,

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## DISCUSSION

### Invention

The Applicants have discovered that injuries to the peritoneum caused by repeated administration of a conventional peritoneal dialysate can be prevented by administering a dialysate containing adenosine triphosphate (ATP), see the first paragraph on page 1 of the specification.

Peritoneal dialysate solutions are used for patients in advanced stages of renal failure who cannot sufficiently remove body wastes, specification, page 1, lines 11 *ff*. A peritoneal dialysis solution containing a high concentration of glucose is introduced into the peritoneum for a period of 5-6 hours to osmotically adsorb body wastes and is subsequently removed (along with the absorbed wastes), specification, page 2, lines 15-19. However since patients are treated with peritoneal dialysis over a long period of time this process can cause hardening of the peritoneum or peritonitis due to repeated exposure to a high concentration of glucose contained in the peritoneal dialysate, specification, page 2, lines 9 *ff*. The inventors discovered that use of a peritoneal dialysate containing adenosine triphosphate (ATP) reduces peritoneal injuries, see the paragraph bridging pages 2-3 of the specification.

### Main Issue—Rejection under 35 U.S.C. §103

Claims 11-36 were rejected under 35 U.S.C. 103(a) as being unpatentable over Isono, et al., U.S. Patent No. 5,871,477. The main issue in this case is simple. The Examiner has misinterpreted the prior art as disclosing or suggesting a peritoneal dialysate containing adenosine triphosphate (ATP). The obviousness rejection is based on the Examiner's misinterpretation of the prior art teachings in

col. 2, lines 5-47 of Isono which he continues to assert disclose or suggest a peritoneal dialysate containing adenosine triphosphate (ATP). On page 3, lines 14-16, the Examiner states:

**Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preserving solution can be added to said peritoneal dialysate (see col. 2, lines 5-46, especially lines 34-46).**

Only the paragraph at col. 2, lines 5-21 of Isono describes a peritoneal dialysate. Two separate paragraphs spanning col. 2, lines 22-47, including lines 34-46 relied upon by the rejection, describe organ-preserving solutions and components of organ-preserving solutions like ATP that may be added to an organ-preserving solution. These last two paragraphs relied upon by the Examiner have nothing to do with peritoneal dialysates. As clearly exemplified by Isono in col. 2, peritoneal dialysates and organ-preserving solutions contain different ingredients, for example, a peritoneal dialysate contains high concentrations of glucose not present in the organ-preserving solution described by Isono and lacks the heparin found in organ preserving solution exemplified by Isono. The paragraphs in col. 2, lines 22-47 of Isono describe ingredients commonly found in organ-preserving solutions including anticoagulants like heparin. ATP is disclosed at col. 2, line 41 as one possible ingredient of an organ-preserving solution. ATP is simply not disclosed as an ingredient of a peritoneal dialysate. There is no support for the Examiner's assertion that Isono discloses or suggests that adenosine triphosphate solution "can be added to said peritoneal dialysate". Moreover, Isono does not confuse these different types of electrolyte solutions and no one skilled in the medical arts would have confused them.

Isono is primarily directed to a medical container containing an electrolyte solution and is not directed to formulating new types of electrolyte solutions. In

conjunction with disclosure of the container, Isono incidentally describes different types of electrolyte solutions that the medical container might hold such as “a body fluid replenisher”, “a dialysate” and “an electrolyte solution”, it does not disclose a peritoneal dialysate solution containing ATP, does not provide any motivation for adding ATP to a peritoneal dialysate, and consequently, cannot provide a reasonable expectation for the superior properties of a peritoneal dialysate containing ATP.

These facts have been pointed out to the Examiner several times, most recently in the response filed January 6, 2010, yet the Examiner persistently maintains that Isono, col. 2, lines 5 to 46 discloses or suggests a peritoneal dialysate that contains ATP, not recognizing that ATP mentioned in col. 2 is only described as an ingredient for an organ-preservation solution.

Since Isono does not disclose a peritoneal dialysate containing ATP either in col. 2 or elsewhere, provide any motivation for adding ATP to a peritoneal dialysate, or provide a reasonable expectation of success for reducing peritoneal injury by adding ATP to a peritoneal dialysate, this rejection cannot be sustained.

Rejection—35 U.S.C. §112, second paragraph

Claim 34 was rejected under 35 U.S.C. 112, second paragraph, as indefinite for use of the phrase “a conventional peritoneal dialysis solution that does not contain adenosine triphosphate and adenosine triphosphate”. This phrase simply refers to a composition containing two components (i) a conventional peritoneal dialysis solution that does not contain adenosine triphosphate” and (ii) adenosine triphosphate which together provide “a peritoneal dialysate containing ATP” as disclosed on page 3, lines 11-12 of the specification. Page 9, 2<sup>nd</sup>

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paragraph, of the specification also discloses admixture of a conventional dialysate with adenosine triphosphate. Moreover, the art applied by the Examiner establishes that conventional peritoneal dialysate solutions not containing adenosine triphosphate were well-known in the art, see Isono, U.S. Patent No. 5,871,477, col. 2, lines 10-16. Therefore, this phrase when read in light of the specification and prior art would have been clear to one of skill in the art at the time of invention. Consequently, this rejection cannot be sustained.

Conclusion

The Applicants respectfully request withdrawal of the two remaining rejections and allowance of this case.

Respectfully submitted,

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